

## **VESSEL AGITATOR ASSEMBLY**

### **DESCRIPTION**

#### **BACKGROUND OF THE INVENTION**

##### *Field of the Invention*

5           The present invention generally relates to an agitator assembly for shaking vessels that are present in a transportation assembly within an automated immunoassay analyzer system.

##### *Background Description*

10           Immunoassay analyzer systems perform chemical tests to determine the presence of a specific antibody or antigen in a sample of biological material such as blood or urine. During the performance of these tests, automated analyzers dilute samples, add reagents, agitate and incubate the test vessels. Agitation is required to mix the samples with the reagent. The agitation also assists to increase the reaction rate when one of the  
15           reagents is bound to a solid phase which can be the interior surface of the assay tube itself or a bead or a suspension of microparticles. Current agitator implementations may provide fins within a vessel, such as the dilution well, as described in Babson et al. 5,723,092, actively impact the vessels as in Babson et al. 5,885,529, or shake the vessels as in Babson et  
20           al. 5,316,726.

#### **SUMMARY OF THE INVENTION**

It is an object of the invention to provide an apparatus and method

to perform agitation of test vessels in an automated immunoassay analyzer in a simple, passive manner.

It is another object of this invention to provide an apparatus and method to perform agitation within an incubation chamber.

5 It is still another object of the invention to provide an apparatus and method to perform agitation of vessels used in an automated immunoassay analyzer which reduces the requirements for specialized tubes or tube processing equipment.

10 According to the invention, a agitator assembly is provided within a transportation assembly of the automated immunoassay analyzer (e.g., a carousel, belt, chain, or other device which moves vessels between stations). The test vessel agitator assembly allows test vessels to be placed in and removed from the transportation assembly. While test vessels are being transported within the automated immunoassay analyzer via the  
15 transportation assembly, the test vessels are passively bumped by the agitator assembly, thereby agitating the contents. This agitation can occur when the test vessel contains a variety of different samples (e.g., blood, plasma, urine, serum, etc.), as well as a variety of other constituents such as diluted samples, reagent, assay bead and/or the like.

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## **BRIEF DESCRIPTION OF THE DRAWINGS**

The foregoing and other objects, aspects and advantages will be better understood from the following detailed description of a preferred embodiment of the invention with reference to the drawings, in which:

- 25 Figure 1 is an overview of an automated immunoassay analyzer.  
Figure 2 is an expanded view of the transportation assembly.  
Figure 3 shows the test vessel conveyor element.  
Figure 4 shows the test vessel agitator assembly.  
Figure 5 shows the motion of the test vessel within the transportation assembly as it is moved along the agitator assembly.

## **DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION**

Referring now to the drawings, and more particularly to Figure 1, which shows an automated immunoassay analyzer as a complex system with numerous subsystems that allow the tests to be performed without the continuous monitoring and intervention of a technician. The technician selects the tests to be performed for each sample and enters this information via the control subsystem 101. The control subsystem 101 manages the other subsystems by sending command and control information via the control bus 102. Samples of biological material (e.g., blood, urine, plasma, etc.) are placed by the technician in the sample subsystem 104. The samples within the sample subsystem 104 can be diluted prior to making measurements or can be tested in the undiluted state depending on direction from the control subsystem 101. The bead subsystem 105 adds the appropriate substrate having a bound "analyte binding compound" to the test vessel. Preferably, the substrate is present in the form of one or more beads having adhered thereto a compound for binding the analyte of interest from the sample under test (e.g., via antigen-antibody binding, etc.). The reagent subsystem 103 adds the specified reagent to the test vessel. The selection of bead and reagent for each sample is managed by the control subsystem 101 based on the type of test to be performed on each sample. These subsystems include identification capabilities such as, for example, bar code readers or RF readers that read the bar code or RFID identification information on the reagent containers, bead containers and sample containers to ensure the correct components are added to each test vessel for testing. The test vessel is moved within the analyzer via the transfer subsystem 108. Once the selected components are added to the test vessel, the incubator subsystem 106 incubates and agitates the test vessel as managed by the control subsystem 101. The

preferred incubator operation is described in more detail in the co-pending application, Multipath Incubator Serial No. 10/\_\_\_\_,\_\_\_\_; however, it should be understood that this invention can be employed in numerous incubator and non-incubator applications (e.g., luminometer subsystem, or region prior to or after the incubator) depending on the design requirements for the vessel transportation assembly. The vessel is then washed and transferred via the transfer subsystem 108 to the luminometer subsystem 107. The luminometer subsystem 107 selects the test vessel and presents it to the detection mechanism. The luminometer operation is described in more detail in the co-pending application, "Rotary Luminometer," Serial No. 10/\_\_\_\_,\_\_\_\_; however, it should be understood that this invention can be used in combination with a variety of devices that make readings on components within a test vessel (e.g., devices that read fluorescence, chemiluminescence, phosphorescence, and/or color). After the read operation is performed, the test vessel is discarded.

Referring now to Figure 2, there is shown an expanded view of a preferred embodiment of the automated immunoassay analyzer transportation assembly 11. Within the transportation assembly 11, the transportation assembly base 1 contains the test vessel agitator 3 mounted against the side wall of the transportation assembly base 1. However, it should be understood that in some applications of the inventions, the test vessel agitator 3 may be free standing or not affixed to assembly base 1. The conveyor element 2 is also mounted in the transportation assembly base 1. The conveyor element 2 is preferably mounted such that it is able to rotate around the mounting wheels 4 that hold the conveyor element 2 in the transportation assembly base 1. However, it should be understood that the path to be traveled by the conveyor element 2 can vary considerably within the practice of this invention and that in some applications traversing around mounting wheels may not be required (e.g., a simple back and forth pathway). In addition, the transportation assembly base 1 allows test vessels (not shown) to be placed in and removed from the test

vessel transportation assembly 11.

5 The conveyor element 2, shown in Figure 3, preferably comprises multiple test vessel holders 6 attached together on a flexible belt 5. It is the belt 5 that is rotated around the mounting wheels 4 and the test vessel holders 6 that travel adjacent to the test vessel agitator 3. The number of test vessels the holders 6 and the configuration of test vessel holders 6 can vary within the practice of this invention.

10 The test vessel agitator 3 is shown in more detail in Figure 4. The support element 7 is a rigid structure upon which the agitator elements 8 are mounted. The agitator elements 8 may be a single piece or multiple pieces that allow contact with the test vessel holders 6. The test vessel agitator 3 is preferably attached to the transportation assembly base 1 by fasteners 9 located along the length of the agitator elements 8 and the support element 7. The agitator elements 8 are preferably made of a rigid material that has ridges and troughs along the horizontal length. The agitator elements 8 function to provide a series of "bumps" that bump the test vessels horizontally as they are transported linearly by the conveyor element 2.

20 Figure 5 shows the performance of the test vessel agitator 3 as the conveyor element 2 moves. The belt 5 travels in the direction indicated by the arrow C. As the belt 2 moves, the test vessels 10 held by test vessel holders 6 move side to side as indicated by arrows A and B while being transported in the direction of arrow C. This side to side motion of the test vessels 10 causes the contents to be shaken while it is moving within the transportation assembly 11. Movement of the test vessels 10 as described by arrows A and B is approximately perpendicular to the movement of the conveyor element 2 described by arrow C.

25 In a preferred embodiment, the transportation assembly 11 can be positioned within an incubator (not shown) inside an automated immunoassay analyzer. Thus, as the test vessels are being incubated, they can be agitated passively simply by linear movement using the conveyor

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element 2. The base 1 could serve as an insulated portion of the incubator (not shown).

While movement of the conveyor 2 is shown in direction C in Figure 4, it should also be understood that in some applications the conveyor 2 may move in forward and reverse directions, with each direction of movement causing agitation by deflection of the vessels in the A and B directions. Figure 5 also shows the agitator elements 8 can have varying sloped troughs and projections although the preferred embodiment is to match the maximum number of vessels to the number of bumps thus achieving a better density of shaking. Having varying distances between troughs or projections as well as varying depths for the troughs can assist in having a more random agitation. However, it should be clear that the projections and troughs could also be uniform in character within the practice of this invention. Or, in some applications, the agitator elements 8 might be configured to provide lighter or harder agitation effects at different locations along the transportation assembly 11 by having projections and troughs of less extreme and more extreme variances (distance between bottom of trough and peak of projection), respectively.

The passive agitation of this invention might also be employed in other chemical analyzers which would benefit from having contents of vessels be agitated to assure proper mixing of the vessel contents after addition of reagents.

While the invention has been described in terms of a single preferred embodiment, those skilled in the art will recognize that the invention can be practiced with modification within the spirit and scope of the appended claims.